PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING Received 21 SEP 2004

PCT

To:
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NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of mailing *(day/month/year)*	11 AUGUST 2004 (11.08.2004)
Applicant's or agent's file reference	**IMPORTANT NOTIFICATION**
PCTA/MEDI/2	

International application No.	International filing date *(day/month/year)*	Priority date *(day/months/year)*
PCT/KR2003/000922	**09 MAY 2003 (09.05.2003)**	09 MAY 2002 (09.05.2002)

Applicant

MEDIGENES et al

1. The applicant is hereby notified that International Preliminary Examining Authority transmits here with the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report(but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details in the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/KR Korean Intellectual Property Office 920 Dunsan-dong, Seo-gu, Daejeon 302-701, Republic of Korea	Authorized officer COMMISSIONER
Facsimile No. 82-42-472-7140	Telephone No. 82-42-481-5198

Form PCT/IPEA/416 (July 1992)

COPY FOR IB

PATENT COOPERATION TREATY

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Rec'd PCT/PTO 21 SEP 2004

REC'D 24 AUG 2004

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Artcle 36 and Rule 70)

Applicant's or agent's file reference PCTA/MEDI/2	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. **PCT/KR2003/000922**	International filing date *(day/month/year)* **09 MAY 2003 (09.05.2003)**	Priority date *(day/month/year)* 09 MAY 2002 (09.05.2002)
International Patent Classification (IPC) or national classification and IPC **IPC7 A61K 35/16**		
Applicant **MEDIGENES et al**		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

   [X] This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 3 sheets.

3. This report contains indications relating to the following items:

   - I [X] Basis of the report
   - II [ ] Priority
   - III [ ] Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV [ ] Lack of unity of invention
   - V [X] Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI [ ] Certain documents cited
   - VII [ ] Certain defects in the international application
   - VIII [ ] Certain observations on the international application

Date of submission of the demamd	Date of completion of this report
05 DECEMBER 2003 (05.12.2003)	10 AUGUST 2004 (10.08.2004)
Name and mailing address of the IPEA/KR Korean Intellectual Property Office 920 Dunsan-dong, Seo-gu, Daejeon 302-701, Republic of Korea Facsimile No. 82-42-472-7140	Authorized officer WON, Ho Joon Telephone No. 82-42-481-8293

Form PCT/IPEA/409 (cover sheet) (July 1998)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International aplication No.
PCT/KR2003/000922

I. Basis of the report

1. With regard to the elements of the international application:*

- [ ] the international application as originally filed
- [X] the description:
  pages 1 - 28 , as originally filed
  pages _____ , filed with the demand
  pages _____ , filed with the letter of _____
- [X] the claims:
  pages _____ , as originally filed
  pages _____ , as amended (together with any statment) under Article 19
  pages _____ , filed with the demand
  pages 29 - 30-1 , filed with the letter of 05/12/2003
- [X] the drawings:
  pages 1 - 15 , as originally filed
  pages _____ , filed with the demand
  pages _____ , filed with the letter of _____
- [ ] the sequence listing part of the description:
  pages _____ , as originally filed
  pages _____ , filed with the demand
  pages _____ , filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language English which is

- [ ] the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- [X] the language of publication of the international application(under Rule 48.3(b)).
- [ ] the language of the translation furnished for the purposes of international preliminary examination(under Rules 55.2 and/ or 55.3).

3. With regard to any **nucleotide** and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- [ ] contained inthe international application in written form.
- [ ] filed together with the international application in computer readable form.
- [ ] furnished subsequently to this Authority in written form.
- [ ] furnished subsequently to this Authority in computer readable form
- [ ] The statement that the subsequently furnished written sequence listing does not go beyond the disc losure in the international applicationas as filed has been furinshed.
- [ ] The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. [ ] The amendments have resulted in the cancellation of:
   - [ ] the description, pages _____
   - [ ] the claims, Nos. _____
   - [ ] the drawings, sheet _____

5. [ ] This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box(Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed." and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item I and annexed to this report.*

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1 - 6	YES
	Claims		NO
Inventive step (IS)	Claims	1 - 6	YES
	Claims		NO
Industrial applicability (IA)	Claims	1 - 6	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

The following documents are referred to;

D1: JP 07-267992 A
D2: JP 03-240738 A
D3: VOLCHEGORSKII IA ET AL., "Changes in the antioxidative activity of blood serum in inflammation". In; Vopr Med Khim.1997 Jul-Aug;43(4)

1. Novelty
Claim 1 relates to a pharmaceutical composition for the treatment of wounds containing a pharmaceutically effective amount of blood plasma as an active agent.

D1 discloses a pharmaceutical composition for the treatment of wounds containing a protein, PHBP-70 obtained from blood plasma of mammals as an active agent. Though the active agent of D1 is also obtained from blood plasma of mammals as that of the present invention, D1 and the present invention are different in that the art of the present claim is characterized by containing several components in blood plasma.

D2 discloses the technical feature of formulating a medication for the treatment of wounds as a cream, ointments, gels, liquids or patches, but does not disclose the active agent as disclosed in the present invention. In addition, D3 discloses an effect of anti-inflammation of a serum, but does not disclose the effect as a practical agent for wounds treatment. Thus, the invention of claim 1 is novel, and claims 2-6 dependent on claim 1 are also novel under PCT Article 33(2).

(Continued on Supplemental Sheet)

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of:

Box V

2. Inventive Step

For the analysis of the inventive step, D1 is considered to be the closest prior art.

The present invention is the same as D1 in the purpose of providing a new pharmaceutical composition for the treatment of wounds.

However, the present invention is different from D1 in an active agent for the treatment of wounds regardless of the similarity of the source of the active agent. The active agent of the present invention is blood plasma itself, compared with a protein, PHBP-70 isolated from blood plasma of mammals of D1. The components of blood plasma are already well-known, containing proteins and inorganic substances including many enzymes, hormone and growth factors.

D1 discloses that a protein, PHBP-70 can be used as an agent for the treatment of wounds on a base of proliferation of fibroblasts, but does not disclose that blood plasma can be used as an agent for the treatment of wounds and that blood plasma shows an effect of the formulation of granulation tissue and an effect of angiogenesis. Accordingly, the subject matter of the present invention cannot be readily defined by a person skilled in the art with the teaching of D1.

While the effect of the treatment of wounds of the present pharmaceutical composition is supported by the formulation of granulation tissue and angiogenesis as represented in experimental examples 1-8, the effect of the treatment of wounds is supported by the proliferation of fibroblasts in D1. It is generally perceived by a person skilled in the art with the knowledge about a various and complicated mechanisms of treating wounds, that the formulation of granulation tissue and angiogenesis do not depend on the proliferation of fibroblasts. In other words, the formulation of granulation tissue and angiogenesis are achieved by a different mechanism from the mechanism of proliferation of fibroblasts. Accordingly, the effect of the present invention cannot be easily foreseen by a person skilled in the art with the teaching of D1. Thus, the present invention is considered to involve an inventive step, the subject matter of claims 1-6 does involve an inventive step in the sense of Article 33(3) PCT.

3. Industrial Applicability
Claims 1 to 6 meet the criteria set out PCT Article 33(4).

WHAT IS CLAIMED IS:

1. A pharmaceutical composition for the treatment of wounds, comprising a pharmaceutically effective amount of blood plasma as an active agent.

2. The pharmaceutical composition according to claim 1, wherein pH is in the range of 3.5 to 6.6

3. The pharmaceutical composition according to claim 1, wherein the active agent is derived from livestock.

4. The pharmaceutical composition according to claim 1, wherein it is topically administered.

5. The pharmaceutical composition according to claim 1, in the form of creams, ointments, gels, liquids or patched.

6. The pharmaceutical composition according to claim 1, wherein the wounds include contusion or bruise, non-healing traumatic wounds, the disruption by irradiation, abrasion, bone gangrene, laceration, avulsion, penetrated wound, gun shot wound, cutting, burn, cold sores, cutaneous ulcers, xeroderma, skin kefatosis, break, rupture, dermatitis, pain by dermatophyte, wounds by surgery or by vascular disorder, corneal wounds, pressure sore, bed sore, certain conditions associated with diabetes such as diabetic cutaneous disorder and with poor circulation, chronic ulcers, suture site caused by plastic

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surgery, spinal traumatic wounds, gynecological wounds, chemical wounds and acne.

7. The pharmaceutical composition according to claims 1 or 6, which is used at an amount of from 0.01 to 0.1 g/cm^2 in the treatment of full thickness defect wounds.

8. A pharmaceutical composition for the treatment of wounds, comprising a pharmaceutically effective amount of blood serum as an active agent.

9. The pharmaceutical composition according to claim 8, wherein pH is in the range of 3.5 to 6.6

10. The pharmaceutical composition according to claim 8, wherein the active agent is derived from livestock.

11. The pharmaceutical composition according to claim 8, wherein it is topically administered.

12. The pharmaceutical composition according to claim 8, in the form of creams, ointments, gels, liquids or patched.

13. The pharmaceutical composition according to claim 8, wherein the wounds include contusion or bruise, non-healing traumatic wounds, the disruption by irradiation, abrasion, bone gangrene, laceration, avulsion, penetrated wound, gun shot wound, cutting, burn, cold sores, cutaneous ulcers, xeroderma, skin kefatosis, break,

rupture, dermatitis, pain by dermatophyte, wounds by surgery or by vascular disorder, corneal wounds, pressure sore, bed sore, certain conditions associated with diabetes such as diabetic cutaneous disorder and with poor circulation, chronic ulcers, suture site caused by plastic surgery, spinal traumatic wounds, gynecological wounds, chemical wounds and acne.

14. The pharmaceutical composition according to claims 8 or 13, which is used at an amount of from 0.01 to 0.1 g/cm^2 in the treatment of full thickness defect wounds.